health care claims database and the claims and medical charts for a subset of this population were reviewed to extract information pertaining to disease-modifying therapy, corticosteroid therapy, MS-related procedures, and diagnosis and relapse dates. The agreement between the data sources for each type of information was identified. **RESULTS:** From a total population of 11,326 MS patients in the claims database, 300 had their medical records reviewed. Among patients with claims for glatiramer acetate (n = 68), 95.6% also had it indicated in their charts. Claims agreed with charts for 91.8% of patients with a claim for intramuscular interferon β-1a (n = 85), 81.8% of patients with a claim for subcutaneous interferon β-1a (n = 55), and 87.5% of patients with a claim for interferon β-1b (n = 48). Methylprednisolone was the most commonly indicated corticosteroid in both data sources, and among patients with evidence of a methylprednisolone fill in the claims (n = 114), 66.7% also had a prescription indicated in their chart. Most patients with claims-based evidence of MS-related procedures also had them indicated in their charts: 71.0% with MRI, 81.0% with lumbar puncture, and 66.7% with evoked potential testing. For both diagnosis and relapse dates, at least half of the patients had perfect agreement. **CONCLUSIONS:** Claims and medical charts provide complementary information with a degree of overlap. Claims appear to approximate chart data with regard to certain MS-related variables, such as dates and disease-modifying therapy, but the data sources also provide unique information which might be differentially suited to addressing diverse research questions.

PND40

THE IMPORTANCE OF GUIDELINES FOR CLINROS: THE ADAS-COG, A CASE STUDY

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OBJECTIVES: Since its development in the 80's, variations of the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog), a Clinician-Reported Outcome (ClinRO) measure, have been used to monitor disease progression and treatment efficacy in Alzheimer's disease. The objective of this study was to identify all versions used as a basis for translation in Mapi Institute projects and to take stock of existing translations. **METHODS:** The review was based on all ADAS-Cog translation projects performed by Mapi Institute. **RESULTS:** Sixteen projects were identified representing a total of 70 languages and 219 translations. Translations were based on 11 source versions which differed in terms of content (number of items, order of items and instructions), and format. The number of items ranged from 11 to 15. Four studies used 13 items, but only in two cases the same items were used but in a different order. Four studies used 12 items: only two studies used the same items (with a different list of words for the Word Recognition Task), but again in a different order. Format and instructions differed in all cases. In most projects the source version provided by the sponsor was a single document mixing instructions with the rater and response forms. Only in 3 cases the original consisted in a separate instruction manual and response forms. With regard to available translations, more than one translation was identified in 56 of the 70 available languages and in one language as many as 7 translations. **CONCLUSIONS:** The abundance of different versions of the same questionnaire both in its original US English form as in translation makes comparisons between studies or pooling of data difficult for both researchers and users. In the light of FDA's recent PRO guidance it would be beneficial to demand the same scientific rigor when using ClinROs in international studies.

PND41

THE EFFECT OF MULTIPLE COMPARISONS ADJUSTMENTS IN ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE BY WORK STATUS

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OBJECTIVES: Explore the effect of adjusting for multiple comparisons in analyzing outcome variables between more than two strata. **METHODS:** Health-related quality of life (HRQoL) via SF-12 Health Survey was measured at baseline for 191 patients in a U.S. multiple sclerosis observational study. HRQoL was summarized in two continuous variables: Physical Component Score (PCS-12) and Mental Component Score (MCS-12). Patient work status was expressed by one categorical variable with four values: Working Full-time (W), Working Part-time (WP), Not Working due to MS (NW-MS), Not Working due to other reasons (NW). Generalized linear models were used to measure the overall association HRQoL and work status. Pairwise comparisons were conducted between the HRQoL means with respect to each of the four categories of work status. The Bonferroni method was used to control the familywise error rate under multiple comparisons test. **RESULTS:** Overall association between Work Status and HRQoL was statistically significant (p-values: <.001 for all measures), suggesting that HRQoL differs by work status. Pairwise comparisons showed that only the NW-MS group was statistically significantly different from all other groups (all p-values <.001) in PCS-12 and different from W and WP groups in MCS-12 (p-value: W = 0.03, WP = < .001), while all other comparisons were not significantly different from each other. If the Bonferroni adjustment is not applied, the pairwise comparisons lead to more differences being significant (p-value: W vs WP = 0.04 in PCS-12 and MCS-12). **CONCLUSIONS:** Even though the overall association between two variables may be statistically significant, if the categorical variable has more than two categories, then applying multiple comparisons adjustments to all pairwise comparisons more appropriately tests the statistical significance of the differences between these individual categories. Neglecting to account for the fact that multiple comparisons are being made may lead to erroneous conclusions about differences in outcomes.

SENSORY SYSTEMS DISORDERS – Clinical Outcomes Studies

PSS1

BEVACIZUMAB FOR NEO-VASCULAR AGE RELATED MACULAR DEGENERATION—EVIDENCE SUMMARY

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OBJECTIVES: To evaluate evidence on effectiveness of intravitreal Avastin for neo-vascular age related macular degeneration (AMD). **METHODS:** We searched the Medline database for articles on bevacizumab for neo-vascular AMD, published between January 1, 2005 and September 1, 2009. The search criteria were English language manuscripts, human studies and search terms "bevacizumab", "Avastin", "age-related macular degeneration", "ARMD", "AMD","intra-vitreal" as a major heading. Boolean operators were used to combine the search terms. Studies in which primary outcome measures were visual acuity (VA) and central retinal thickness (CRT) were included for review. Two reviewers independently selected studies, assessed methodological quality using Scottish Intercollegiate Grading Network (SIGN) system. **RESULTS:** Overall, there were 520 citations, of which only 216 were relevant after title and abstract screening. Sixty-seven manuscripts were finally included for review, of which three were systematic reviews, three were randomized Controlled Trials (RCT), 49 were pre-post/ non-randomized studies and 13 were studies on safety and adverse effect. Three RCTs show bevacizumab to be more effective than PDT (with or without triamcinolone). However, these RCTs had several methodological issues; evidence from these RCT's was of moderate quality. Several pre-post and non-randomized studies have also suggested the effectiveness of bevacizumab, but these studies had several design limitations and hence the quality of evidence was deemed poor. Pooled outcome estimates, showed bevacizumab therapy,on average, improved VA by nine EDTRS letters and reduced CRT by 90 µm. Incidence of adverse events was low, similar to ranibizumab. Currently moderate (grade B) to poor quality of evidence is available in support of bevacizumab for neo-vascular AMD. **CONCLUSIONS:** Based on current evidence (grade B) off-label Intravitreal bevacizumab seems to be safe and effective for the treatment of neo-vascular AMD in the short term, especially for underserved and financially challenged communities.

SENSORY SYSTEMS DISORDERS – Cost Studies

PSS2

RETURN ON INVESTMENT OF ABLATIVE FRACTIONAL LASERS

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OBJECTIVES: Conduct a return on investment (ROI) analysis of 8 ablative fractional lasers used for cosmetic facial plastic surgery from the perspective of a facial plastic surgeon. **METHODS:** We identified 8 of the largest (based on sales volume) ablative fractional lasers for this analysis. ROI is (ΣTotal Revenue–ΣTotal Cost)/(ΣTotal Cost) and is defined as the additional dollar returned from each dollar invested. Revenue was estimated as price per procedure multiplied by total number of procedures in a year. Total cost is a composite of purchase price and operating costs. In the base case analysis two purchase options were assumed 1) a 5 year lease with a $0 down payment and 2) a 3 year lease with a $0 down payment. In addition to monthly lease payments, included in the total cost estimate were service contracts, labor costs, and disposables. Sensitivity analyses were preformed to account for variability in cost and revenue assumptions. **RESULTS:** Revenue for each laser was estimated to be $51,072/year. Under a 5 year lease, the assumed total cost of each laser ranged from $115,827–$240,597. This is compared to the total cost under a 3 year lease of each laser which ranged from $74,364–$124,878. Average ROI under the 5 year lease term was .54 and ROI varied between –.03 (most expensive laser) and 1 (least expensive laser). The average 3 year ROI was .08, and ROI varied between -.35 (most expensive laser) and .38 (least expensive laser). **CONCLUSIONS:** Based on the assumptions of our analysis the laser with highest ROI was the least expensive laser. While ROI is an important financial it should not be the sole means by which to determine a purchase. Physicians must also consider the clinical effectiveness of each laser and their own clinical judgment when making such decisions.

PSS3

THE ECONOMIC IMPACT OF DRY EYE DISEASE IN THE UNITED STATES

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OBJECTIVES: Evaluate the annual cost of Dry Eye Diseases (DED) care in the United States from both a societal and a payer's perspective **METHODS:** A decision-tree model was developed to estimate the annual cost for managing a cohort of DED patients with differing severity of symptoms and treatments utilizing data collected from survey and the literature. The direct costs included over the counter (OTC) medications, cyclosporine, punctal plugs, physician visits, and nutrition complements. The indirect costs were computed based on the self-reported productivity loss including absenteeism and presenteeism. Multiple-one way sensitivity analysis was employed to evaluate the impact of changes in parameters within their 95% confidence intervals on the cost estimate. **RESULTS:** In the base-case analysis, the total mean annual direct